

CLAIMS

1. A process for preparing bacterial OMVs, comprising a step of ultrafiltration.
2. The process of claim 1, wherein the ultrafiltration step is performed on an aqueous suspension of OMVs that have been prepared from bacteria.
- 5 3. The process of any preceding claim, wherein the ultrafiltration step results in diafiltration.
4. The process of any preceding claim, wherein the ultrafiltration is cross-flow or tangential flow.
5. The process of any preceding claim, wherein the membrane used for ultrafiltration has a cut-off of about 300kDa.
6. The process of any preceding claim, wherein the OMVs are sterilised after ultrafiltration.
- 10 7. The process of claim 6, wherein the sterilisation is by filter sterilisation.
8. A process for preparing bacterial OMVs, comprising the steps of: (a) cultivating bacterial cells; (b) collecting and/or concentrating the cultivated cells; (c) disrupting the outer membranes of the cultivated cells; and (d) preparing OMVs by the method of any one of claims 1 to 7.
9. The process of any preceding claim, further comprising the step of combining the OMVs with a pharmaceutical carriers and/or adjuvants and/or stabiliser.
- 15 10. The process of any preceding claim, wherein the bacterium for OMV preparation is Gram-negative.
11. The process of claim 10, wherein the bacterium is *Neisseria meningitidis*.
12. The process of claim 11, wherein the bacterium is serogroup B *N.meningitidis*.
- 20 13. The process of claim 12, wherein the bacterium is a B:4:P1.4 strain, a B:4:P1.15 strain, a B:4:P1.19,15 strain, a B:4:P1.7b,4 strain strain or a B:15:P1.7,16 strain.
14. The process of any one of claims 11 to 13, wherein the *N.meningitidis* has one or more mutations to decrease or knockout expression of a gene product.
- 25 15. The process of claim 14, wherein the gene product is Cps, CtrA, CtrB, CtrC, CtrD, ExbB, ExbD, FrpB, GalE, HtrB, MsbB, LbpA, LbpB, LpxK, NMB0033, OpA, OpC, PhoP, PilC, PmrE, PmrF, PorA, PorB, rmpM, SiaA, SiaB, SiaC, SiaD, SynA, SynB, SynC, TbpA and/or TbpB.
16. A process for purifying bacterial OMVs, wherein the process does not include a centrifugation step in which the OMVs are pelleted.
17. Bacterial OMVs obtainable by the process of any preceding claim.

18. A pharmaceutical composition comprising the OMVs of claim 17 and a pharmaceutically acceptable carrier.
19. The composition of claim 18, comprising an aluminium hydroxide adjuvant and a histidine buffer.
- 5 20. The composition of claim 18 or claim 19, wherein the composition is substantially free from whole bacteria.
21. A vial containing the composition of claim 18 or claim 19 or claim 20.
22. A syringe containing the composition of claim 18 or claim 19 or claim 20.
23. A method for raising an immune response in a patient, comprising administering an immunogenic dose of the composition of claim 18 or claim 19 or claim 20.